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NOTICE OF ALLOWANCE AND FEE(S) DUE

23448 7590 04/29/2008

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER	
KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/29/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,702	12/20/2005	David Hone	4115-178	4972

TITLE OF INVENTION: RECOMBINANT DOUBLE-STRANDED RNA PHAGES AND USES THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$720	$300	$0	$1020	07/29/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

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TITLE OF INVENTION: RECOMBINANT DOUBLE-STRANDED RNA PHAGES AND USES THEREOF

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nonprovisional	YES	$720	$300	$0	$1020	07/29/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
KINSEY WHITE, NICOLE ERIN	1648	435-320100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/29/2008

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/525,702	HONE, DAVID	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the reply filed on March 2, 2008*.

2. ☒ The allowed claim(s) is/are *1-4,6-30,62,63 and 79*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 12/5/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven Hultquist on April 3, 2008.

The application has been amended as follows:

In the claims:

1. (Previously Presented) A recombinant double stranded RNA phage (rdsRP) comprising a double stranded RNA eukaryotic expression cassette for expression in eukaryotic cells, the rdsRP comprising:

at least one genomic segment of a double stranded RNA phage (dsgP) and an internal ribosome entry site (IRES) nucleotide sequence incorporated into the at least one genomic segment of the dsRP.

2. (Previously Presented) The rdsRP according to claim 1, further comprising at least one passenger gene sequence incorporated into the at least one genomic segment of the dsRP.

3. (Previously Presented) The rdsRP according to claim 1, wherein the IRES is inserted into at least one of three dsRNA genomic segments of the dsRP selected from the group consisting of segment L, segment M and segment S.

4. (Original) The rdsRP according to claim 2, wherein the passenger gene and the IRES are functionally linked.

5. (Cancelled)

6. (Previously Presented) The rdsRP according to claim 1, wherein said eukaryotic expression cassette is an alpha virus expression cassette.

7. (Original) The rdsRP according to claim 2, wherein the passenger gene encodes for an immunogen.

8. (Original) The rdsRP according to claim 1, wherein the dsRP is Phi-6, Phi-8, or Phi-13.

9. (Previously Presented) The rdsRP according to claim 2, wherein the rdsRP genomic segment is expressed and amplified in a bacterial host strain.

10. (Previously Presented) The rdsRP according to claim 7, wherein the rdsRP genomic segment further comprises an adjuvant as an additional passenger gene.

11. (Previously Presented) The rdsRP according to claim 7, wherein the rdsRP genomic segment further comprises a cytokine.

12. (Original) The rdsRP according to claim 7, wherein the immunogen is foreign or endogenous.

13. (Original) The rdsRP according to claim 12, wherein the immunogen is foreign and is a member selected from the group consisting of viral proteins, bacterial proteins, parasite proteins, cytokines, chemokines, immunoregulatory agents, and therapeutic agents.

14. (Previously Presented) The rdsRP according to claim 13, wherein the immunogen originates from a viral pathogen, bacterial pathogen, or parasitic pathogen.

15. (Original) The rdsRP according to claim 14, wherein the immunogen originates from a viral pathogen comprising a member selected from the group consisting of Orthomyxoviruses, Retroviruses, Herpesviruses, Lentiviruses, Rhabdoviruses, Picornoviruses, Poxviruses, Rotavirus and Parvoviruses.

16. (Original) The rdsRP according to claim 13, wherein the viral protein is a member selected from the group consisting of: human immunodeficiency virus antigens, Nef, Rev, mutant derivatives of Tat, Tat-A31-45, Pol, T cell epitopes of gp120, and B cell epitopes of gp120, chimeric derivatives of HIV-1-CD4, chimeric Env-CD4, chimeric gp120-CD4, hepatitis B surface antigen, rotavirus antigens, influenza virus antigens, and herpes simplex virus antigens.

17. (Original) The rdsRP according to claim 12, wherein the immunogen is endogenous and is a member selected from the group consisting of cellular proteins, immunoregulatory agents, therapeutic agents, tumor immunogens, autoimmune immunogens and parts thereof.

18. (Original) The rdsRP according to claim 17, wherein the tumor immunogen comprises a member selected from the group consisting of PSA, CEA, MAGE-1 and tyrosinase.

19. (Original) The rdsRP according to claim 10, where the adjuvant comprises a member selected from the group consisting of: A subunit of cholera toxin, bacterial

adenosine diphosphate-ribosylating exotoxins, pertussis toxin S1 subunit, adenylate cyclase-hemolysins of *Bordetella pertussis*, and parts thereof.

20. (Previously Presented) The rdsRP according to claim 11, wherein the cytokine is a member selected from the group consisting of; interleukin-4, IL-5, IL-6, IL-10, IL-12_{p40}, IL-12_{p70}, TGFβ and TNFα.

21. (**Currently Amended**) The rdsRP according to claim 2, wherein the IRES comprises a member selected from the group consisting of: the IRES located at nucleotides 665-1251 in pIRES2-EGFP (SEQ ID NO: 6), IRES from plasmid pCITE4a (SEQ ID NO: 7), IRES from plasmid pSVIRES-N (SEQ ID NO: 4), IRES of the 3'-untranslated region of the mRNA for the beta subunit of mitochondrial H+-ATP synthase (SEQ ID NO: 8), SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5.

22. (Original) A composition comprising the rdsRP according to claim 4.

23. (Previously Presented) The composition according to claim 22, wherein the rdsRP comprises an alpha virus expression cassette.

24. (Original) The composition according to claim 22, wherein the passenger gene encodes for an immunogen.

25. (Original) The composition according to claim 22, wherein the dsRP is Phi-6, Phi-8, or Phi-13.

26. (Previously Presented) The composition according to claim 22, wherein the rdsRP genomic segment is amplified in a bacterial host strain.

27. (Previously Presented) The composition according to claim 22, wherein the rdsRP genomic segment further encodes for an adjuvant as a second passenger gene.

28. (Previously Presented) The composition according to claim 22, wherein the rdsRP genomic segment further encodes for a cytokine.

29. (Original) The composition according to claim 22, wherein the immunogen is foreign or endogenous.

30. (Original) The composition according to claim 29, wherein the immunogen is foreign and is a member selected from the group consisting of viral proteins, bacterial proteins, parasite proteins, cytokines, chemokines, immunoregulatory agents, and therapeutic agents.

31.-61. (Cancelled)

62. (Previously Presented) A method of inducing an immune response or biological activity comprising administering to a subject the rdsRP according to claim 4 via bacterial vector delivery thereof to cells or tissues of said subject, in a sufficient amount to express an effective amount of encoded passenger gene.

63. (Previously Presented) The method according to claim 62, wherein rdsRP is delivered with a pharmaceutically acceptable carrier or diluent.

64.-78. (Cancelled)

79. (Previously Presented) A live bacterium comprising at least one dsRP according to claim 4.

80. (Cancelled)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648